II. REMARKS

As an initial matter, Applicants gratefully acknowledge the telephone interview conducted on December 3, 2009 between Applicants' attorney, Wesley Ashton, and Examiner Kevin Orwig (571-270-5869) regarding the Information Disclosure Statement (IDS) filed on July 30, 2009. Specifically, the Examiner did not consider the New Food Industry article, Vol. 31, pp. 9-15 (1989), (hereafter the "New Food Industry Article") submitted with the IDS of July 30, 2009 even though it was submitted with a partial English translation. The Examiner explained to Applicants' attorney that the reference was not considered because it did not correspond to the number of pages listed on the USPTO form PTO/SB/08 provided by Applicants. Applicants' attorney explained for the Examiner that the New Food Industry Article was filed with a partial English translation, as described on the corresponding USPTO form PTO/SB/08, so that the extra pages pertain to the partial English translation.

In view of the above clarification, Examiner Orwig informed Applicants' attorney that the Examiner will consider the New Food Industry Article. Therefore, **Applicants respectfully request that the Examiner indicate the New Food Industry Article has been considered by returning a corrected USPTO form PTO/SB/08, initialed by the Examiner, documenting that the New Food Industry Article has, in fact, been considered by the Examiner**.

Claims 19-28 have been withdrawn because they pertain to a non-elected invention. Applicants contend that upon allowance of the invention of Group I, claims 1-18, that the invention of non-elected Group II, claims 19-28, should be rejoined with the allowed claims in accordance with MPEP § 821.04 because the claims of Group II depend upon the claims of Group I, and, therefore, incorporate all of the subject matter of at least one allowed claim.

By the present paper, claims 12 and 18 have been cancelled without prejudice, claims 1-8, 13 and 14 have been amended, and new claims 41 and 42 have been added. Specifically, claims 1-8, 13 and 14 have been amended to address a typographical error, which has no further limiting effect on the scope of claims 1-8, 13 and 14. Claims 7 and 13 have been further amended to incorporate the subject matter of claims 12 and 18, respectively. Therefore, claims 7 and 13 now have the same scope as previous claims 12 and 18, respectively.

New claims 41 and 42 depend upon claims 7 and 13, respectively, and additionally recite "a sweet material selected from the group consisting of high fructose corn syrup, fructose, aspartame, stevia sweetener and acesulfam K" as supported by ¶ [0045] of Applicants' disclosure as originally filed.

The present amendment adds no new matter to the above-captioned application.

A. <u>The Invention</u>

The present invention pertains broadly to a reducer of blood glucose level increase, a reducer of body fat accumulation, and a food material. In accordance with an embodiment of the present invention, a reducer of blood glucose level increase is provided that includes elements recited by independent claim 1. In accordance with another embodiment of the present invention, a reducer of blood glucose level increase is provided that includes elements recited by independent claim 2. In accordance with yet another embodiment of the present invention, a reducer of blood glucose level increase is provided that includes elements recited by independent claim 3.

In accordance with another embodiment of the present invention, a reducer of body fat accumulation is provided that includes elements recited by independent claim 4. In accordance with yet another embodiment of the present invention, a reducer of body fat

accumulation is provided that includes elements recited by independent claim 5. In accordance with still another embodiment of the present invention, a reducer of body fat accumulation is provided that includes elements recited by independent claim 6.

In accordance with another embodiment of the present invention, a food material is provided that includes elements recited by independent claim 7. In accordance with yet another embodiment of the present invention, a food material is provided that includes elements recited by independent claim 8. In accordance with still another embodiment of the present invention, a food material is provided that includes elements recited by independent claim 13. In accordance with another embodiment of the present invention, a food material is provided that includes elements recited by independent claim 14. Various other embodiments, in accordance with the present invention, are recited by the dependent claims.

An advantage provided by the various embodiments of the present invention is that palatinose is employed to have beneficial effects on a individual's metabolism by, for example, reducing the level of glucose increase after ingesting a carbohydrate, and/or reducing the accumulation of fat after ingesting a carbohydrate.

B. The Rejections

Claims 1-3, 7 and 8 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.

Claims 1-18 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Lina et al. (B. A. R. Lina et al., 40 FOOD AND CHEM. TOX. 1375-1381 (2002), hereafter the "Lina Article"). Claims 1-18 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Bucke et al. (U.S. Patent 4,587,119, hereafter the "Bucke Patent"). Claims 1-18 also stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Brendel et al. (U.S. Patent Application Publication No. 2002/0192344 A1, hereafter the "Brendel Publication").

Claims 29-40 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over the Lina Article in view of Shimizu (U.S. Patent Application Publication No. 2003/0180432, hereafter the "Shimizu Publication").

Applicants respectfully traverse the Examiner's rejections and request reconsideration of the above-captioned application for the following reasons.

C. Applicants' Arguments

i. The Section 112 Rejection

The Examiner contends that claims 1-18 and 29-40 are indefinite because claims 1-3, 7 and 8 recite "5 g or more of isomaltulose per 60 kg of body weight of an individual as an active ingredient" and because clams 4-6, 13 and 14 recite "10 g or more of isomaltulose per 60 kg of body weight of an individual as an active ingredient" (Office Action, dated November 18, 2009, at 16, lines 15-21). The Examiner erroneously argues that these limitations are "analogous to method steps in a product claim since they imply the active step of administering the composition to an individual." The Examiner's arguments are flawed, and the indefiniteness rejection must be withdrawn, for the following reasons.

First, U.S. Patent 4,374,841 (See Information Disclosure Statement (IDS) filed herewith) recites, in claim 6,

> "[a] pharmaceutical or veterinary composition for treating arterial hypertension comprising as active ingredient at least one pyridoxine derivative according to claims 1, 2, 3, 4 or 5 in association with a pharmaceutical carrier or excipient therefor in a daily dosage of about 300 mg per 60 kg of body weight." (emphasis added).

U.S. Patent 4,400,387 (See IDS filed herewith) recites, in claim 7,

> "[a] pharmaceutical or veterinary composition for treating physiological disturbances consequent upon an excess of uric acid and consequent upon disorders of the immunization system containing, as active principle, at least one indolizine derivative according to claim 1 or 2, in association with a pharmaceutical carrier or excipient therefor, in daily dosage of about 300 mg per 60 kg of body weight." (emphasis added)

Thus, at least two U.S. patents (i.e., U.S. Patent 4,374,841 and U.S. Patent 4,400,387) claim compositions that are defined in terms of "mg per 60 kg of body weight." It is a well-settled proposition that the claims of a U.S. patent are presumed to be valid. American Hoist & Derrick Co. v. Sowa & Sons, Inc., 220 U.S.P.Q. 763, 771 (Fed. Cir. 1984).

Claims 1-18 and 29-40 of the present application claim a composition that limits the amount of isomaltulose in "g... per 60 kg of body weight," whereas claims 6 and 7 of U.S. Patent 4,374,841 and U.S. Patent 4,400,387, respectively, each recite a composition that defines one or more components of the composition in terms of "mg per 60 kg of body weight." A person of ordinary skill in the art would know that 1 g = 1000 mg so that there is no substantial difference in terms of compliance with 35 U.S.C. § 112, second paragraph, between the limitations recited by the present application and those recited by U.S. Patent 4,374,841 and U.S. Patent 4,400,387. In other words, because claim 6 of U.S. Patent 4,374,841, and claim 7 of U.S. Patent 4,400,387, are presumed to be in compliance with 35 U.S.C. § 112, second paragraph, then the Examiner must conclude that claims 1-18 and 29-40 of the present application are also in compliance with 35 U.S.C. § 112, second paragraph.

Second, for a claim to comply with 35 U.S.C. § 112, second paragraph, it must (1) set forth what the Applicant regards as the invention and (2) it must do so with sufficient particularity and distinctness so as to be sufficiently "definite." Solomon v. Kimberly-Clark Corp., 55 U.S.P.Q.2d 1279, 1282 (Fed. Cir. 2000). During patent prosecution, definiteness of a claim may be analyzed by consideration of evidence beyond the patent specification, including the inventor's statements to the Patent and Trademark Office. Id. In this case, it is common practice in the art to dose the amount of an active ingredient of a composition with respect to body weight of a recipient as evident from the Abstract and page 1378, right col., lines 15-19, of the Lina Article (of record), claim 6 of U.S. Patent 4,374,841, claim 7 of U.S. Patent 4,400,387, and Davis's Drug Guide : Pediatric Dosage Calculations, *at*

http://www.drugguide.com/ddo/ub/view/Davis-Drug-Guide/, downloaded February 11, 2010 (filed herewith as "Exhibit F"). Therefore, a person of ordinary skill in the art would instantly understand the scope of the subject matter claimed when the amount of one or more components of the composition are defined in terms of body weight. Solomon v. Kimberly-Clark Corp., 55 U.S.P.Q.2d 1279, 1282 (Fed. Cir. 2000)(Federal Circuit explaining that the definiteness of the language employed by the claims must be analyzed not in a vacuum, but in light of the teachings of the prior art and in view of the particular application disclosure as it would be interpreted by one possessing ordinary level of skill in the pertinent art).

Third, Applicants' claims recite the content of isomaltulose in terms of body weight, which is not a "method limitation" as the Examiner contends. Furthermore, the Examiner misconstrues the claimed invention when stating that the "plain meaning of the claim requires different amounts of isomaltulose per individual," (Office Action, dated November 18, 2009, at 17, lines 6-8), because dosing by body weight is a technique for normalizing dosages. As is known in the art, body weight may affect serum blood levels of a drug when the drug is given at a set dose (in grams) independent of body weight (See, e.g., M. Chen et al., *Comparative Pharmacokinetics and Pharmacodynamic Target Attainment of Ertapenem in Normal-Weight, Obese, and Extremely Obese Adults*, 50 ANTIMICROBIAL AGENTS AND CHEMOTHERAPY 1222-1227 (2006), filed herewith as "Exhibit G," FIG. 1 and Abstract). As would be known by persons of ordinary skill in the art, determining dosage by body weight normalizes the dose and, therefore, renders the pharmacologic effect of a pharmaceutically active agent more predictable.

On the other hand, a composition that includes an amount of active ingredient not normalized for body weight may not result in a desired pharmacological effect. For example, if 5 gm of isomaltulose were given to a 60 kg individual, for example, the dose normalized by weight would be 0.0833 g/kg, whereas if 5 gm of isomaltulose were given to a 120 kg

individual, then the dose normalized by weight is only 0.04167 g/kg. Thus, the 5 gm isomaltulose dose received by the 60 kg individual may be sufficient to decrease the rise in blood glucose when given with another sugar whereas the 5 gm isomaltulose dose given to the 120 kg may be insufficient to trigger such an effect. As is known in the art, pharmacologically active substances generally have a threshold dose, below which they do not have a biological effect (See, e.g., Figure 4 of Kenneth A. Skau, *Teaching Pharmacodynamics: An Introductory Module on Learning Dose-Response Relationships*, 68 AMERICAN JOURNAL OF PHARMACEUTICAL EDUCATION 1-6 (2004), a copy of which is filed herewith as "Exhibit H"). Applicants' original specification, ¶ [0055], describes a threshold dose of isomaltulose of "5g or more per 60kg of body weight of an individual."

In sum, dosing isomaltulose by body weight ensures that every individual receiving the composition gets the same amount of isomaltulose normalized for body weight. Therefore, the Examiner is incorrect when asserting that Applicants' claimed invention is indefinite on the grounds that individuals are not getting the same dose because, pound for pound, individuals are getting the same dose.

For all of the above reasons, the Examiner has failed to establish a prima facie case of indefiniteness against Applicants' claims. On the contrary, Applicants' claims 1-11, 13-17 and 29-42 are in full compliance with 35 U.S.C. § 112.

ii. The Section 102 Rejections

Anticipation under 35 U.S.C. § 102 requires showing the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim. Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick, 221 U.S.P.Q. 481, 485 (Fed. Cir. 1984). In this case, the Examiner has failed to establish a prima facie case of

anticipation against Applicants' claimed invention because neither the Lina Article, the Bucke Patent, nor the Brendel Publication, teaches or suggests, each and every element of the claimed invention, arranged as in the claims.

iii. The Lina Article

The Lina Article pertains to a review of biological and toxicological studies of isomaltulose. The Lina Article characterizes isomaltulose as a reducing disaccharide found in honey, sugar cane juice, and in man-made products such as treacles and food-grade molasses (See Lina Article, at 1375, left col., lines 2-7). The Lina Article discloses that rises in blood glucose, fructose and insulin levels following isomaltulose ingestion are slower than those caused by sucrose because isomaltulose undergoes slower hydrolyzation in the gastrointestinal tract (Lina Article, at 1377, left col., lines 3-9). The Lina Article also discloses that rats fed a mixture of isomaltulose and sucrose over thirteen weeks did not die or exhibit behavioral changes (Lina Article, at 1377, right col., line 46, to 1378, left col., line 2).

The Lina Article, however, does not teach, or even suggest, (i) a

> "reducer of blood glucose level increase…wherein "when said reducer is ingested by an individual before or after or simultaneously with consuming a carbohydrate having an α-1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides, said reducer reduces an increase in blood glucose level of the individual caused by consuming said carbohydrate,"

as recited by independent claim 1, (ii) a

> "reducer of blood glucose level increase…wherein when said reducer is ingested by an individual before or after or simultaneously with consuming at least one foodstuff selected from the group consisting of sucrose, wheat flour, starch, dextrin and high fructose corn syrup, said reducer reduces an increase in blood glucose level of the individual caused by consuming said foodstuff,"

as recited by independent claim 2, (iii) a

"reducer of blood glucose level increase...wherein when said reducer is ingested by an individual before or after or simultaneously with consuming food, said reducer reduces an increase in blood glucose level of the individual caused by consuming said food,

as recited by claim 3, (iv) a

"reducer of body fat accumulation...wherein when said reducer is ingested by an individual before or after or simultaneously with consuming a carbohydrate having an α-1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides, said reducer reduces body fat accumulation resulting from an increase in blood glucose level and insulin secretion of the individual caused by ingesting said carbohydrate,"

as recited by independent claim 4, (v) a

"reducer of body fat accumulation...wherein when said reducer is ingested by an individual before or after or simultaneously with consuming at least one foodstuff selected from the group consisting of sucrose, wheat flour, starch, dextrin and high fructose corn syrup, said reducer reduces body fat accumulation resulting from an increase in blood glucose level and insulin secretion of the individual caused by consuming said foodstuff,

as recited by claim 5, (vi) a

"reducer of body fat accumulation...wherein when said reducer is ingested by an individual before or after or simultaneously with consuming food, said reducer reduces body fat accumulation resulting from an increase in blood glucose level and insulin secretion of the individual caused by consuming said food,"

as recited by claim 6, (vii) a

"food material...wherein the weight (A) of said isomaltulose has a ratio of 10% or more relative to the total weight (B) of carbohydrate contained in said food material, and said isomaltulose is combined so that said isomaltulose is ingested by 5g or more per 60kg of body weight of the individual ingesting the food material, and wherein said food material reduces blood glucose level increase for an individual caused by consuming said foodstuff,"

as recited by independent claim 7, (viii) a

"food material, comprising....at least one foodstuff selected from the group consisting of sucrose, wheat flour, starch, dextrin and high fructose corn syrup...wherein said food material reduces blood glucose level increase for an individual caused by consuming said foodstuff ,"

as recited by independent claim 8, (ix) a

"food material comprising...a foodstuff composed of a carbohydrate

having an α-1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides…wherein the weight (A) of said isomaltulose has a ratio of 20% or more relative to the total weight (B) of carbohydrate contained in said food material, and said isomaltulose is combined so that said isomaltulose is ingested by 10g or more per 60kg of body weight of the individual ingesting the food material, and wherein said food material reduces body fat accumulation resulted from the increase in blood glucose level and insulin secretion of an individual caused by consuming said foodstuff,"

as recited by independent claim 13, and (x) a

"food material comprising… at least one foodstuff selected from the group consisting of sucrose, wheat flour, starch, dextrin and high fructose corn syrup… wherein said food material reduces body fat accumulation resulting from an increase in blood glucose level and insulin secretion of an individual caused by consuming said foodstuff,"

as recited by independent claim 14.

a. The Examiner has Improperly Refused to Give Patentable Weight to the Wherein Clauses of Applicants' Composition Claims

The Examiner contends that the "wherein" clauses of claims 1-11 and 13-17 pertain to an "intended use and desired outcome of ingesting isomaltulose" and are given no patentable weight in accordance with MPEP § 2111.04 (Office Action, dated November 18, 2009, at 4, line 19, to 5, line 6). Applicants strenuously object to the Examiner's refusal to give patentable weight to the wherein clauses for the following reasons.

First, it is a well-established proposition that the claims define the invention, there is no "gist" of the invention, and each and every claimed limitation must be considered when determining patentablility. Vas-Cath Inc. v. Mahurhar, 19 U.S.P.Q.2d 1111, 1118 (Fed. Cir. 1991). Second, the MPEP is not the law, and does not support the proposition asserted by the Examiner, namely, that "wherein" clauses do not merit patentable weight. Third, MPEP § 2111.04 cites and discusses Hoffer v. Microsoft Corp., 74 U.S.P.Q.2d 1481, 1483-84 (Fed. Cir. 2005) in which the Federal Circuit held that the district court properly construed the

"whereby" clause as further limiting the claimed process. Therefore, the Examiner's position is squarely prohibited by the Federal Circuit's decision in Hoffer v. Microsoft Corp. MPEP § 2111.04 also cites Minton v. National Association of Securities Dealers, Inc., 67 U.S.P.Q.2d 1614, 1620 (Fed. Cir. 2003), in which the Federal Circuit held that a "whereby" clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited. As admitted by the Examiner (Office Action, dated November 18, 2009, at 5, lines 5-6), Applicants' claimed invention pertains to a composition and not to a method. Therefore, the Federal Circuit's ruling in Minton v. National Association of Securities Dealers, Inc. regarding method claims cannot be applied to Applicants' composition claims.

It is another well-settled proposition that functional language may be used to define a claimed invention. In re Swinehart, 169 U.S.P.Q. 226, 228 (C.C.P.A. 1971). In this case, Applicants' "wherein" clauses further define the claimed invention in terms of a property or characteristic of the composition under the specific circumstances recited in the claims, namely, to the effect of the composition once ingested. In other words, the "wherein" clauses pertain to how the composition effects the host when metabolized, which is a property of the composition and not merely an intended use.

The Federal Circuit has held that materials may be defined, in part, by various property parameters. E.I. du Pond de Nemours & Co. v. Phillips Petroleum Co., 7 U.S.P.Q.2d 1129, 1133 (Fed. Cir. 1988). In this case, the effect the invention according to claims 1-3, 7 and 8 has on blood glucose is a property of the claimed composition. Likewise, the effect the invention according to claims 4-6, 13 and 14 has on body fat accumulation is a property of the claimed composition. Therefore, the Examiner should give patentable weight to the "wherein" clauses (i) to (x) above because these clauses define various properties of the composition that are used to define, in part, the novel composition.

For all of the above reasons, the Examiner must give patentable weight to the "wherein" clauses recited in the claims. Once the Examiner gives the patentable weight due the "wherein" clauses, the Examiner must withdraw the rejection of the claims under 35 U.S.C. § 102(b) based on the Lina Article because the Lina Article does not teach, or suggest, these claimed features.

b. The Lina Article Fails to Anticipate the Subject Matter of the "Wherein" Clauses Because These Properties are Not Inherent to the Compositions Disclosed by the Lina Article

The Examiner contends that the composition disclosed by the Lina Article "inherently" discloses the claimed properties of the compositions recited by claims 1-8, 13 and 14 because "[p]roducts of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable" and, in support of this proposition, the Examiner cites In re Spada, 15 U.S.P.Q.2d 1655, 1658 (Fed. Cir. 1990), (Office Action, dated November 18, 2009, at 5, lines 16-22). More specifically, the Examiner contends that "any composition comprising isomaltulose would have this property and reads on the claims" (Office Action, dated November 18, 2010, at 5, line 22, to 6, line 1). The Examiner acknowledges Applicants' argument that Applicants' specification supports the requirement of a threshold dose of isomaltulose required to obtain the desired biological effect; however, the Examiner erroneously argues that the biological effect would be present for isomaltulose independent of dose because "[b]elow [the threshold] level of isomaltulose, the effect is still present, it is just not (statistically) significant" (Office Action, dated November 18, 2009, at 8, lines 7-16).

The Examiner's inherency argument is flawed as a matter of fact because it is well-known in the art that dose-response relationship for biologically active substances generally

includes a threshold dose, below which no biological effect occurs (See, e.g., Exhibit H, Figure 4, and page 4, left col., line 1, 10, to right col., line 11). Consequently, a person of ordinary skill in the art would immediately realize it is not inherent to isomaltulose that it will provoke the changes in glucose and fat metabolism recited by Applicants' claims independent of dose as the Examiner contends.

Applicants' specification describes that the ability of isomaltulose to reduce the increase in blood glucose level of an individual who consumed certain types of carbohydrates, or foodstuffs, or foods, depends on exceeding a minimum dose of the isomaltulose (See Applicants' English translation filed July 1, 2004 of Applicants' specification as originally filed, ¶¶ [0055] and [0065]). Therefore, not all compositions containing isomaltulose possess the property pertaining to "reduc[ing] an increase in blood glucose level of the individual" as recited in claims 1-3, 7 and 8. Likewise, the ability of isomaltulose to reduce body fat accumulation in an individual who consumed certain types of carbohydrates, or foodstuffs, or foods, depends on exceeding a higher minimum dose of the isomaltulose than the minimum dose required to have an effect on blood glucose levels following ingestion of the certain types of carbohydrates, foodstuffs or foods (Applicants' English translation filed July 1, 2004 of Applicants' specification as originally filed, ¶¶ [0056] and [0076]). Therefore, not all compositions containing isomaltulose possess the property pertaining to "reduc[ing] body fat accumulation" as recited in claims 4-6, 13 and 14.

Second, the Federal Circuit has held that a reference may inherently teach subject matter not explicitly disclosed by the reference when the disclosure is sufficient to show that the implicit subject matter is the natural result flowing from the explicitly disclosed subject matter. Continental Can Co. USA Inc. v. Monsanto Co., 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991). However, inherency cannot be established by mere probabilities or possibilities, and the mere fact that a certain thing may result from a given set of circumstances is insufficient.

Id. The Federal Circuit has ruled that inherency is a question of fact. In re Napier, 34 U.S.P.Q.2d 1782, 1784 (Fed. Cir. 1995).

In this case, the Lina Article reports that, for rats, ingestion of up to 8.1 g/kg body weight/day of isomaltulose in a mixture with sucrose did not affect body fat accumulation with respect to controls (Lina Article, at 1377, right col., line 46, to 1378, left col., line 15). The Lina Article does not teach, or suggest, that ingestion of isomaltulose in combination with a carbohydrate having an α-1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides, or with at least one foodstuff selected from the group consisting of sucrose, wheat flour, starch, dextrin and high fructose corn syrup, or with food, results in the reduction in fat accumulation from ingesting these substances. On the contrary, the Lina Article only discloses that ingesting isomaltulose in combination with sucrose does not affect fat accumulation.

With respect to the affect of isomaltulose on blood glucose levels when ingested with a carbohydrate having an α-1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides, sucrose, wheat flour, starch, dextrin, high fructose corn syrup, or food, the Lina Article generally discloses that no differences in "clinical chemistry" as noted between control rats (sucrose only supplemented diet) and test rats (diet supplemented with isomaltulose and sucrose mixture), (Lina Article, at 1377, right col., line 46, to 1378, left col., line 7). Therefore, the Lina Article does not provide a sufficient disclosure from which a person of ordinary skill in the art may conclude that the blood glucose increase reducing property of the claimed invention may be inferred as "inherent."

For all of the above reasons, the "wherein" clauses (i) to (x) of Applicants' claims should be construed as limitations material to patentability, and that these limitations are

neither "inherent" to all isomaltulose containing compositions nor "inherent" to the isomaltulose containing compositions disclosed by the Lina Article.

c. The Lina Article Fails to Teach the Claimed Range

While the Lina Article discloses feeding rats up to 8.1 g/kg body weight/day of isomaltulose (Lina Article, at 1378, left col., lines 11-15) and giving humans as little as 0.25 g/kg/dose of oral isomaltulose (Lina Article, at 1378, right col., lines 26-32), the Lina Article does not teach, or suggest, a threshold dose of (xi) "5 g or more of isomaltulose per 60 kg of body weight of an individual as an active ingredient" as recited by claims 1-3, 7 and 8, and (xii) "10 g or more of isomaltulose per 60 kg of body weight of an individual as an active ingredient" as recited by claims 4-6, 13 and 14.

d. Claims 7 and 13

Claim 7 pertains to a "food material" that satisfies the relationship wherein

> "the weight (A) of said isomaltulose has a ratio of 20% or more relative to the total weight (B) of carbohydrate contained in said food material, and said isomaltulose is combined so that said isomaltulose is ingested by 10g or more per 60kg of body weight of the individual ingesting the food material,"

and has the property wherein

> "said food material reduces body fat accumulation resulted from the increase in blood glucose level and insulin secretion of an individual caused by consuming said foodstuff."

The Examiner has not shown that the composition disclosed by the Lina Article satisfies the relationship between (A) and (B) recited by claim 7. Therefore, the Examiner cannot infer that the composition disclosed by the Lina Article has the body fat accumulation reducing property recited by claim 7 because the composition disclosed by the Lina Article and the composition recited by claim 7 are not the same composition.

Claim 13 pertains to a "food material" that satisfies the relationship wherein

> "wherein the weight (A) of said isomaltulose has a ratio of 20% or more relative to the total weight (B) of carbohydrate contained in said food material, and said isomaltulose is combined so that said isomaltulose is ingested by 10g or more per 60kg of body weight of the individual ingesting the food material,"

and has the property wherein

> "said food material reduces body fat accumulation resulted from the increase in blood glucose level and insulin secretion of an individual caused by consuming said foodstuff."

The Examiner has not shown that the composition disclosed by the Lina Article satisfies the relationship between (A) and (B) recited by claim 13. Therefore, the Examiner cannot infer that the composition disclosed by the Lina Article has the body fat accumulation reducing property recited by claim 13 because the composition disclosed by the Lina Article and the composition recited by claim 13 are not the same composition.

On the contrary, while the Lina Article discloses feeding rats a mixture of isomaltulose and sucrose for 13 weeks, the Lina Article discloses that no difference in body weight, haematology, clinical chemistry and urinalysis was observed between test rats fed a diet supplemented with an isomaltulose/sucrose mixture and control rats fed a diet supplemented with sucrose (Lina Article, at 1377, right col., line 46, to 1378, left col., line 15). Therefore, a person of ordinary skill in the art would realize that the Lina Article does not teach, or suggest, that "said food material reduces body fat accumulation" as recited by clams 7 and 13.

e. Additional Limitations Not Disclosed by the Lina Article

As admitted by the Examiner (Office Action, dated November 18, 2009, at 13, lines 21-22), the Lina Article also fails to teach, or suggest, (xiii) "the one or more components include a carrier, and the carrier is a gum" as recited by claims 29, 31, 33, 35, 37 and 39, and (xiv) "the one or more components include a pharmaceutical ingredient, and the pharmaceutical ingredient is a vitamin" as recited by claims 30, 32, 34, 36, 38 and 40. The

Lina Article also does not teach, or suggest, "a sweet material selected from the group consisting of high fructose corn syrup, fructose, aspartame, stevia sweetener and acesulfam K" as recited by claims 41 and 42.

For all of the above reasons, the Lina Article fails to anticipate the subject matter recited by claims 1-11, 13-17 and 29-42 of the above-captioned application.

iv. The Bucke Patent

The Bucke Patent discloses a "method of reducing dental plaque formation with products for human or animal consumption using isomaltulose sucrose substitute," wherein isomaltulose is used as a whole or partial replacement for sucrose in products for human or animal consumption (See Abstract of the Bucke Patent). The Bucke Patent discloses various products, such as toffee humbugs, shortcake biscuits, marzipan, toffee, meringues, pudding, sponge cakes, canned fruits, plum jam, toothpaste, chewing gum, and lemonade that contain isomaltulose (Bucke Patent, col. 6, line 49, to col. 12, line 11). The Bucke Patent discloses that the plum jam includes isomaltulose and sucrose (Bucke Patent, Example 11, col. 10, line 61, to col. 11, line 12).

The Bucke Patent does not teach, or suggest, (i) a

> "reducer of blood glucose level increase…wherein "when said reducer is ingested by an individual before or after or simultaneously with consuming a carbohydrate having an α-1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides, said reducer reduces an increase in blood glucose level of the individual caused by consuming said carbohydrate,"

as recited by independent claim 1, (ii) a

> "reducer of blood glucose level increase…wherein when said reducer is ingested by an individual before or after or simultaneously with consuming at least one foodstuff selected from the group consisting of sucrose, wheat flour, starch, dextrin and high fructose corn syrup, said reducer reduces an increase in blood glucose level of the individual caused by consuming said foodstuff,"

as recited by independent claim 2, (iii) a

"reducer of blood glucose level increase...wherein when said reducer is ingested by an individual before or after or simultaneously with consuming food, said reducer reduces an increase in blood glucose level of the individual caused by consuming said food,

as recited by claim 3, (iv) a

"reducer of body fat accumulation...wherein when said reducer is ingested by an individual before or after or simultaneously with consuming a carbohydrate having an α-1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides, said reducer reduces body fat accumulation resulting from an increase in blood glucose level and insulin secretion of the individual caused by ingesting said carbohydrate,"

as recited by independent claim 4, (v) a

"reducer of body fat accumulation...wherein when said reducer is ingested by an individual before or after or simultaneously with consuming at least one foodstuff selected from the group consisting of sucrose, wheat flour, starch, dextrin and high fructose corn syrup, said reducer reduces body fat accumulation resulting from an increase in blood glucose level and insulin secretion of the individual caused by consuming said foodstuff,

as recited by claim 5, (vi) a

"reducer of body fat accumulation...wherein when said reducer is ingested by an individual before or after or simultaneously with consuming food, said reducer reduces body fat accumulation resulting from an increase in blood glucose level and insulin secretion of the individual caused by consuming said food,"

as recited by claim 6, (vii) a

"food material...wherein the weight (A) of said isomaltulose has a ratio of 10% or more relative to the total weight (B) of carbohydrate contained in said food material, and said isomaltulose is combined so that said isomaltulose is ingested by 5g or more per 60kg of body weight of the individual ingesting the food material, and wherein said food material reduces blood glucose level increase for an individual caused by consuming said foodstuff,"

as recited by independent claim 7, (viii) a

"food material, comprising....at least one foodstuff selected from the group consisting of sucrose, wheat flour, starch, dextrin and high fructose corn syrup...wherein said food material reduces blood glucose level increase for an individual caused by consuming said foodstuff ,"

as recited by independent claim 8, (ix) a

"food material comprising...a foodstuff composed of a carbohydrate

having an α-1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides…wherein the weight (A) of said isomaltulose has a ratio of 20% or more relative to the total weight (B) of carbohydrate contained in said food material, and said isomaltulose is combined so that said isomaltulose is ingested by 10g or more per 60kg of body weight of the individual ingesting the food material, and wherein said food material reduces body fat accumulation resulted from the increase in blood glucose level and insulin secretion of an individual caused by consuming said foodstuff,"

as recited by independent claim 13, and (x) a

"food material comprising… at least one foodstuff selected from the group consisting of sucrose, wheat flour, starch, dextrin and high fructose corn syrup… wherein said food material reduces body fat accumulation resulting from an increase in blood glucose level and insulin secretion of an individual caused by consuming said foodstuff,"

as recited by independent claim 14.

a. The Examiner has Improperly Refused to Give Patentable Weight to the Wherein Clauses of Applicants' Composition Claims

The Examiner contends that the "wherein" clauses of claims 1-11 and 13-17 pertain to an "intended use and desired outcome of ingesting isomaltulose" and are given no patentable weight in accordance with MPEP § 2111.04 (Office Action, dated November 18, 2009, at 4, line 19, to 5, line 6). Applicants strenuously object to the Examiner's refusal to give patentable weight to the wherein clauses for all of the same reasons as discussed *supra* in Section II(C)(iii)(a).

For all of the above reasons, the Examiner must give patentable weight to the "wherein" clauses recited in the claims. Once the Examiner gives the patentable weight due the "wherein" clauses, the Examiner must withdraw the rejection of the claims under 35 U.S.C. § 102(b) based on the Bucke Patent because the Bucke Patent does not teach, or suggest, these claimed features.

b. The Bucke Patent Fails to Anticipate the Subject Matter of the "Wherein" Clauses Because These Properties are Not Inherent to the Compositions Disclosed by the Bucke Patent

The Examiner appears to contend that the composition disclosed by the Bucke Patent "inherently" discloses the claimed properties of the compositions recited by claims 1-8, 13 and 14 because "[p]roducts of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable" and, in support of this proposition, the Examiner cites In re Spada, 15 U.S.P.Q.2d 1655, 1658 (Fed. Cir. 1990), (Office Action, dated November 18, 2009, at 5, lines 16-22; and at 10, lines 21-22). More specifically, the Examiner contends that "any composition comprising isomaltulose would have this property and reads on the claims" (Office Action, dated November 18, 2010, at 5, line 22, to 6, line 1). The Examiner acknowledges Applicants' argument that Applicants' specification supports the requirement of a threshold dose of isomaltulose required to obtain the desired biological effect; however, the Examiner erroneously argues that the biological effect would be present for isomaltulose independent of dose because "[b]elow [the threshold] level of isomaltulose, the effect is still present, it is just not (statistically) significant" (Office Action, dated November 18, 2009, at 8, lines 7-16).

The Examiner's inherency argument is flawed as a matter of fact for all of the reasons discussed *supra* in Section II(C)(iii)(b). In addition, the Bucke Patent is silent with respect to dose of isomaltulose. Therefore, the Examiner's inherency argument with respect to the Bucke Patent is untenable and must be withdrawn because Applicants' specification, and the claimed invention, recite a threshold amount of isomaltulose.

For all of the above reasons, the "wherein" clauses (i) to (x) of Applicants' claims should be construed as limitations material to patentability, and that these limitations are

neither "inherent" to all isomaltulose containing compositions nor "inherent" to the isomaltulose containing compositions disclosed by the Bucke Patent.

c. The Bucke Patent Fails to Teach the Claimed Range

The Bucke Patent is completely silent regarding dose of isomaltulose. Therefore, the Bucke Patent does not teach, or suggest, a threshold dose of (xi) "5 g or more of isomaltulose per 60 kg of body weight of an individual as an active ingredient" as recited by claims 1-3, 7 and 8, and (xii) "10 g or more of isomaltulose per 60 kg of body weight of an individual as an active ingredient" as recited by claims 4-6, 13 and 14. **The Examiner has failed to acknowledge and address this deficiency in the disclosure of the Bucke Patent**.

d. Claims 7 and 13

Claim 7 pertains to a "food material" that satisfies the relationship wherein

> "the weight (A) of said isomaltulose has a ratio of 20% or more relative to the total weight (B) of carbohydrate contained in said food material, and said isomaltulose is combined so that said isomaltulose is ingested by 10g or more per 60kg of body weight of the individual ingesting the food material,"

and has the property wherein

> "said food material reduces body fat accumulation resulted from the increase in blood glucose level and insulin secretion of an individual caused by consuming said foodstuff."

The Examiner has not shown that the composition disclosed by the Bucke Patent satisfies the relationship between (A) and (B) recited by claim 7. Therefore, the Examiner cannot infer that the composition disclosed by the Bucke Patent has the body fat accumulation reducing property recited by claim 7 because the composition disclosed by the Bucke Patent and the composition recited by claim 7 are not the same composition.

Claim 13 pertains to a "food material" that satisfies the relationship wherein

> "wherein the weight (A) of said isomaltulose has a ratio of 20% or more relative to the total weight (B) of carbohydrate contained in said food material, and said isomaltulose is combined so that said isomaltulose is ingested by 10g or more per 60kg of body weight of the individual ingesting the food material,"

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The Examiner has not shown that the composition disclosed by the Bucke Patent satisfies the relationship between (A) and (B) recited by claim 13. Therefore, the Examiner cannot infer that the composition disclosed by the Bucke Patent has the body fat accumulation reducing property recited by claim 13 because the composition disclosed by the Bucke Patent and the composition recited by claim 13 are not the same composition.

For all of the above reasons, a person of ordinary skill in the art would realize that the Bucke Patent does not teach, or suggest, that "said food material reduces body fat accumulation" as recited by clams 7 and 13.

e. Additional Limitations Not Disclosed by the Bucke Patent

The Bucke Patent also fails to teach, or suggest, (xiii) "the one or more components include a carrier, and the carrier is a gum" as recited by claims 29, 31, 33, 35, 37 and 39, and (xiv) "the one or more components include a pharmaceutical ingredient, and the pharmaceutical ingredient is a vitamin" as recited by claims 30, 32, 34, 36, 38 and 40. The Bucke Patent also does not teach, or suggest, "a sweet material selected from the group consisting of high fructose corn syrup, fructose, aspartame, stevia sweetener and acesulfam K" as recited by claims 41 and 42.

For all of the above reasons, the Bucke Patent fails to anticipate the subject matter recited by claims 1-11, 13-17 and 29-42 of the above-captioned application.

v. <u>The Brendel Publication</u>

The Brendel Publication discloses a "process for preparing a low-calorie food," which involves the step consisting of replacing all or part of the high-calorie substances of the food with an effective quantity, in terms of the reduction of the calorific value, of branched maltodextrins having between 15 and 35% of 1→6 glucoside linkages, a reducing sugar content less than 20%, a polymolecularity index of less than 5 and a number-average molecular mass Mn at most equal to 4500 g/mol (See Abstract of the Brendel Publication). The Brendel Publication discloses how to make low-calorie biscuits, cereal bars, fizzy soft drinks, and bread (Brendel Publication, ¶¶ [0036] to [0113]). The Brendel Publication further discloses that the branched maltodextrins may be simultaneously present with 0.5 to 98% by weight, and preferably 5 to 98% by weight, relative to the total weight of the food, of at least one sugar selected from the group consisting of xylose, fructose, glucose, polydextrose, sucrose, maltose, lactose, isomaltose, isomaltooligosacccharides, isomaltulose, glucose syrups, high-fructose glucose syrups, maltodextrins, fructooligosaccharides and galactooligosaccharides (Brendel Publication, ¶ [0026]).

The Brendel Publication does not teach, or suggest, (i) a

> "reducer of blood glucose level increase…wherein "<u>when said reducer is ingested by an individual before or after or simultaneously with consuming a carbohydrate having an α-1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides, said reducer reduces an increase in blood glucose level of the individual caused by consuming said carbohydrate</u>,"

as recited by independent claim 1, (ii) a

> "reducer of blood glucose level increase…<u>wherein when said reducer is ingested by an individual before or after or simultaneously with consuming at least one foodstuff selected from the group consisting of sucrose, wheat flour, starch, dextrin and high fructose corn syrup, said reducer reduces an increase in blood glucose level of the individual caused by consuming said foodstuff</u>,"

as recited by independent claim 2, (iii) a

"reducer of blood glucose level increase...wherein when said reducer is ingested by an individual before or after or simultaneously with consuming food, said reducer reduces an increase in blood glucose level of the individual caused by consuming said food,

as recited by claim 3, (iv) a

"reducer of body fat accumulation...wherein when said reducer is ingested by an individual before or after or simultaneously with consuming a carbohydrate having an α-1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides, said reducer reduces body fat accumulation resulting from an increase in blood glucose level and insulin secretion of the individual caused by ingesting said carbohydrate,"

as recited by independent claim 4, (v) a

"reducer of body fat accumulation...wherein when said reducer is ingested by an individual before or after or simultaneously with consuming at least one foodstuff selected from the group consisting of sucrose, wheat flour, starch, dextrin and high fructose corn syrup, said reducer reduces body fat accumulation resulting from an increase in blood glucose level and insulin secretion of the individual caused by consuming said foodstuff,

as recited by claim 5, (vi) a

"reducer of body fat accumulation...wherein when said reducer is ingested by an individual before or after or simultaneously with consuming food, said reducer reduces body fat accumulation resulting from an increase in blood glucose level and insulin secretion of the individual caused by consuming said food,"

as recited by claim 6, (vii) a

"food material...wherein the weight (A) of said isomaltulose has a ratio of 10% or more relative to the total weight (B) of carbohydrate contained in said food material, and said isomaltulose is combined so that said isomaltulose is ingested by 5g or more per 60kg of body weight of the individual ingesting the food material, and wherein said food material reduces blood glucose level increase for an individual caused by consuming said foodstuff,"

as recited by independent claim 7, (viii) a

"food material, comprising....at least one foodstuff selected from the group consisting of sucrose, wheat flour, starch, dextrin and high fructose corn syrup...wherein said food material reduces blood glucose level increase for an individual caused by consuming said foodstuff ,"

as recited by independent claim 8, (ix) a

"food material comprising...a foodstuff composed of a carbohydrate

having an α-1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides…wherein the weight (A) of said isomaltulose has a ratio of 20% or more relative to the total weight (B) of carbohydrate contained in said food material, and said isomaltulose is combined so that said isomaltulose is ingested by 10g or more per 60kg of body weight of the individual ingesting the food material, and wherein said food material reduces body fat accumulation resulted from the increase in blood glucose level and insulin secretion of an individual caused by consuming said foodstuff,"

as recited by independent claim 13, and (x) a

"food material comprising… at least one foodstuff selected from the group consisting of sucrose, wheat flour, starch, dextrin and high fructose corn syrup… wherein said food material reduces body fat accumulation resulting from an increase in blood glucose level and insulin secretion of an individual caused by consuming said foodstuff,"

as recited by independent claim 14.

a. The Examiner has Improperly Refused to Give Patentable Weight to the Wherein Clauses of Applicants' Composition Claims

The Examiner contends that the "wherein" clauses of claims 1-11 and 13-17 pertain to an "intended use and desired outcome of ingesting isomaltulose" and are given no patentable weight in accordance with MPEP § 2111.04 (Office Action, dated November 18, 2009, at 4, line 19, to 5, line 6). Applicants strenuously object to the Examiner's refusal to give patentable weight to the wherein clauses for all of the same reasons as discussed *supra* in Section II(C)(iii)(a).

For all of the above reasons, the Examiner must give patentable weight to the "wherein" clauses recited in the claims. Once the Examiner gives the patentable weight due the "wherein" clauses, the Examiner must withdraw the rejection of the claims under 35 U.S.C. § 102(b) based on the Brendel Publication because the Brendel Publication does not teach, or suggest, these claimed features.

b. The Brendel Publication Fails to Anticipate the Subject Matter of the "Wherein" Clauses Because These Properties are Not Inherent to the Compositions Disclosed by the Brendel Publication

The Examiner appears to contend that the composition disclosed by the Brendel Publication "inherently" discloses the claimed properties of the compositions recited by claims 1-8, 13 and 14 because "[p]roducts of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable" and, in support of this proposition, the Examiner cites In re Spada, 15 U.S.P.Q.2d 1655, 1658 (Fed. Cir. 1990), (Office Action, dated November 18, 2009, at 5, lines 16-22; and at 11, line 19, to 12, line 6). More specifically, the Examiner contends that "any composition comprising isomaltulose would have this property and reads on the claims" (Office Action, dated November 18, 2010, at 5, line 22, to 6, line 1). The Examiner acknowledges Applicants' argument that Applicants' specification supports the requirement of a threshold dose of isomaltulose required to obtain the desired biological effect; however, the Examiner erroneously argues that the biological effect would be present for isomaltulose independent of dose because "[b]elow [the threshold] level of isomaltulose, the effect is still present, it is just not (statistically) significant" (Office Action, dated November 18, 2009, at 8, lines 7-16).

The Examiner's inherency argument is flawed as a matter of fact for all of the reasons discussed *supra* in Section II(C)(iii)(b). In addition, the Brendel Publication is silent with respect to dose of isomaltulose. While the Brendel Publication discloses that, per 100 g of dough, there is 6.2 g of branched maltodextrins (Brendel Publication, Table between ¶¶ [0037] and [0038]), the Brendel Publication does not disclose how much dough is used per biscuit. Therefore, a person of ordinary skill in the art would have absolutely no idea how much isomaltulose is dosed per biscuit. Consequently, the Examiner's inherency argument with respect to the Brendel Publication is untenable and must be withdrawn because

Applicants' specification, and the claimed invention, recite a threshold amount of isomaltulose.

For all of the above reasons, the "wherein" clauses (i) to (x) of Applicants' claims should be construed as limitations material to patentability, and that these limitations are neither "inherent" to all isomaltulose containing compositions nor "inherent" to the isomaltulose containing compositions disclosed by the Brendel Publication.

c. The Brendel Publication Fails to Teach the Claimed Range

The Brendel Publication is completely silent regarding dose of isomaltulose. Therefore, the Brendel Publication does not teach, or suggest, a threshold dose of (xi) "5 g or more of isomaltulose per 60 kg of body weight of an individual as an active ingredient" as recited by claims 1-3, 7 and 8, and (xii) "10 g or more of isomaltulose per 60 kg of body weight of an individual as an active ingredient" as recited by claims 4-6, 13 and 14. **The Examiner has failed to acknowledge and address this deficiency in the disclosure of the Brendel Publication**.

d. Claims 7 and 13

Claim 7 pertains to a "food material" that satisfies the relationship wherein

> "the weight (A) of said isomaltulose has a ratio of 20% or more relative to the total weight (B) of carbohydrate contained in said food material, and said isomaltulose is combined so that said isomaltulose is ingested by 10g or more per 60kg of body weight of the individual ingesting the food material,"

and has the property wherein

> "said food material reduces body fat accumulation resulted from the increase in blood glucose level and insulin secretion of an individual caused by consuming said foodstuff."

The Examiner has not shown that the composition disclosed by the Brendel Publication satisfies the relationship between (A) and (B) recited by claim 7. Therefore, the Examiner

cannot infer that the composition disclosed by the Brendel Publication has the body fat accumulation reducing property recited by claim 7 because the composition disclosed by the Brendel Publication and the composition recited by claim 7 are not the same composition.

Claim 13 pertains to a "food material" that satisfies the relationship wherein

> "wherein the weight (A) of said isomaltulose has a ratio of 20% or more relative to the total weight (B) of carbohydrate contained in said food material, and said isomaltulose is combined so that said isomaltulose is ingested by 10g or more per 60kg of body weight of the individual ingesting the food material,"

and has the property wherein

> "said food material reduces body fat accumulation resulted from the increase in blood glucose level and insulin secretion of an individual caused by consuming said foodstuff."

The Examiner has not shown that the composition disclosed by the Brendel Publication satisfies the relationship between (A) and (B) recited by claim 13. Therefore, the Examiner cannot infer that the composition disclosed by the Brendel Publication has the body fat accumulation reducing property recited by claim 13 because the composition disclosed by the Brendel Publication and the composition recited by claim 13 are not the same composition.

For all of the above reasons, a person of ordinary skill in the art would realize that the Brendel Publication does not teach, or suggest, that "said food material reduces body fat accumulation" as recited by clams 7 and 13.

e. Additional Limitations Not Disclosed by the Brendel Publication

The Brendel Publication also fails to teach, or suggest, (xiii) "the one or more components include a carrier, and the carrier is a gum" as recited by claims 29, 31, 33, 35, 37 and 39, and (xiv) "the one or more components include a pharmaceutical ingredient, and the pharmaceutical ingredient is a vitamin" as recited by claims 30, 32, 34, 36, 38 and 40. The Brendel Publication also does not teach, or suggest, "a sweet material selected from the group

consisting of high fructose corn syrup, fructose, aspartame, stevia sweetener and acesulfam K" as recited by claims 41 and 42.

For all of the above reasons, the Brendel Publication fails to anticipate the subject matter recited by claims 1-11, 13-17 and 29-42 of the above-captioned application.

vi. The Section 103 Rejection

A prima facie case of obviousness requires a showing that the scope and content of the prior art teaches each and every element of the claimed invention, and that the prior art provides some teaching, suggestion or motivation, or other legitimate reason, for combining the references in the manner claimed. KSR International Co. v. Teleflex Inc., 127 S.Ct. 1727, 1739-41 (2007); In re Oetiker, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992). In this case, the Examiner has failed to establish a prima facie case of obviousness against claims 29-40 because the Shimizu Publication is not valid prior art, and because the Lina Article, the Bucke Patent, and the Brendel Publication, either alone or in combination, fails to make up the deficiency.

vii. The Lina Article

As conceded by the Examiner (Office Action, dated November 18, 2009, at 13, lines 21-22), the Lina Article fails to teach, or suggest, (xiii) "the one or more components include a carrier, and the carrier is a gum" as recited by claims 29, 31, 33, 35, 37 and 39, and (xiv) "the one or more components include a pharmaceutical ingredient, and the pharmaceutical ingredient is a vitamin" as recited by claims 30, 32, 34, 36, 38 and 40. Neither the Bucke Patent nor the Brendel Publication teach, or suggest, these limitations either.

viii. <u>The Shimizu Publication</u>

The Shimizu Publication discloses "prepared soymilks and soymilk beverages." However, the Shimizu Publication corresponds to U.S. Patent Application No. 10/359,768, filed February 6, 2003. Therefore, the earliest effective date of the Shimizu Publication as prior art is **<u>February 6, 2003</u>**. On the other hand, the above-captioned application was filed on November 18, 2003, and claims priority to JP 2002-334032 filed November 18, 2002, and JP 2003-096395 filed on March 31, 2003, and to JP 2003-386594 filed on November 17, 2003. Certified copies of these three Japanese priority documents were filed with the United States Patent and Trademark Office (USPTO) on April 9, 2004, and Applicants' specification was amended on June 23, 2008 to include the priority claim (See Amendment (B), filed June 23, 2008). In addition, Applicants filed a certified English translation of JP 2002-334032 with the USPTO on July 30, 2009.

In view of the above facts, the above-captioned application is entitled to a priority date of **<u>November 18, 2002</u>** with respect to all subject matter supported by JP 2002-334032. As evident from claims 1-12, and ¶¶ [0050], and Tables 1 and 2 of JP 2002-334032, the subject matter of claims 29-40 is supported by JP 2002-334032. Therefore, the Shimizu Publication is not valid prior art with respect to the embodiments of the invention recited by claims 29-40 of the present application.

With respect to new claims 41 and 42, the subject matter recited by these claims is supported by ¶¶ [0035] and [0038] of JP 2002-334032. Therefore, the Shimizu Publication is not valid prior art with respect to the embodiments of the invention recited by claims 41 and 42 of the present application.

No further comment regarding the Shimizu Publication is believed to be necessary.

ix. Traversing Any Intended "Official Notice"

The Examiner states that "[s]ince Lina teaches the use of isomaltulose in foodstuffs, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include components typically found in edible compositions, such as gums and/or vitamins." (Office Action, mailed November 18, 2009, at 13, line 25, to 14, line 3, emphasis in the original). To the extent the Examiner is giving "Official Notice" of some fact, Applicants object. It is a well-established principle that the Patent Office cannot remedy a deficiency in the teaching of one or more references merely by asserting what is "basic knowledge" in the art; rather, the Patent Office must demonstrate all claim limitations based on substantial evidentiary support. In re Zurko, 59 U.S.P.Q.2d 1693, 1697 (Fed. Cir. 2001). In this case, the Examiner's alleged prior art, namely, the Shimizu Publication, is not valid prior art. Thus, the Examiner cannot remedy this deficiency by unsubstantiated assertions of alleged facts in view of the fact that the Examiner has already failed to substantiate the Official Notice.

x. Summary of the Disclosures

As admitted by the Examiner (Office Action, dated November 18, 2009, at 13, lines 21-22), the Lina Article fails to teach, or suggest, (xiii) "the one or more components include a carrier, and the carrier is a gum" as recited by claims 29, 31, 33, 35, 37 and 39, and (xiv) "the one or more components include a pharmaceutical ingredient, and the pharmaceutical ingredient is a vitamin" as recited by claims 30, 32, 34, 36, 38 and 40. Neither the Bucke Patent nor the Brendel Publication teach, or suggest, these limitations, and the Shimizu Publication is not valid prior art. Therefore, the Examiner's Section 103 rejection is untenable on its face and must be withdrawn.

xi. Additional Comments Regarding the Present Invention and Unexpected Results

Although the Examiner has not evinced any rejection against the claimed invention under 35 U.S.C. § 103, Applicants point out that the present invention provides unexpected results over what is commonly known in the art. The Federal Circuit has held that the common sense of those skilled in the art may demonstrate why some combinations are obvious and others are not. Leapfrog Enterprises, Inc. v. Fisher-Price, Inc., 485 F.3d 1157, 1161 (Fed. Cir. 2007). Furthermore, when an applicant adduces specific data demonstrating substantially improved results, and states that the results are unexpected, then in the absence of evidence to the contrary, applicant has established unexpected results sufficient to prove the invention is nonobvious. In re Soni, 34 U.S.P.Q.2d 1684, 1687-88 (Fed. Cir. 1995). The invention need only be compared to the closest prior art, In re Johnson, 223 U.S.P.Q. 1260, 1264 (Fed. Cir. 1984), however, it is acceptable to compare the invention to subject matter that is closer to the invention than the closest prior art. Ex parte Humber, 217 U.S.P.Q. 265, 266 (Bd. Pat. App. & Inter. 1981).

The present invention is based on the discovery of unknown properties pertaining to a novel palatinose-containing composition that includes "5 g or more of isomaltulose per 60 kg of body weight of an individual as an active ingredient" and "10 g or more of isomaltulose per 60 kg of body weight of an individual as an active ingredient." Novel properties of such novel palatinose-containing compositions include that palatinose reduces the blood glucose level increase caused by ingesting glucose, sucrose, and the like, when palatinose content is "5 g or more of isomaltulose per 60 kg of body weight of an individual" and palatinose reduces body fat accumulation caused by ingesting glucose, sucrose and the like, when palatinose content is "10 g or more of isomaltulose per 60 kg of body weight of an individual as an active ingredient." Furthermore, palatinose reduces the blood glucose level increase

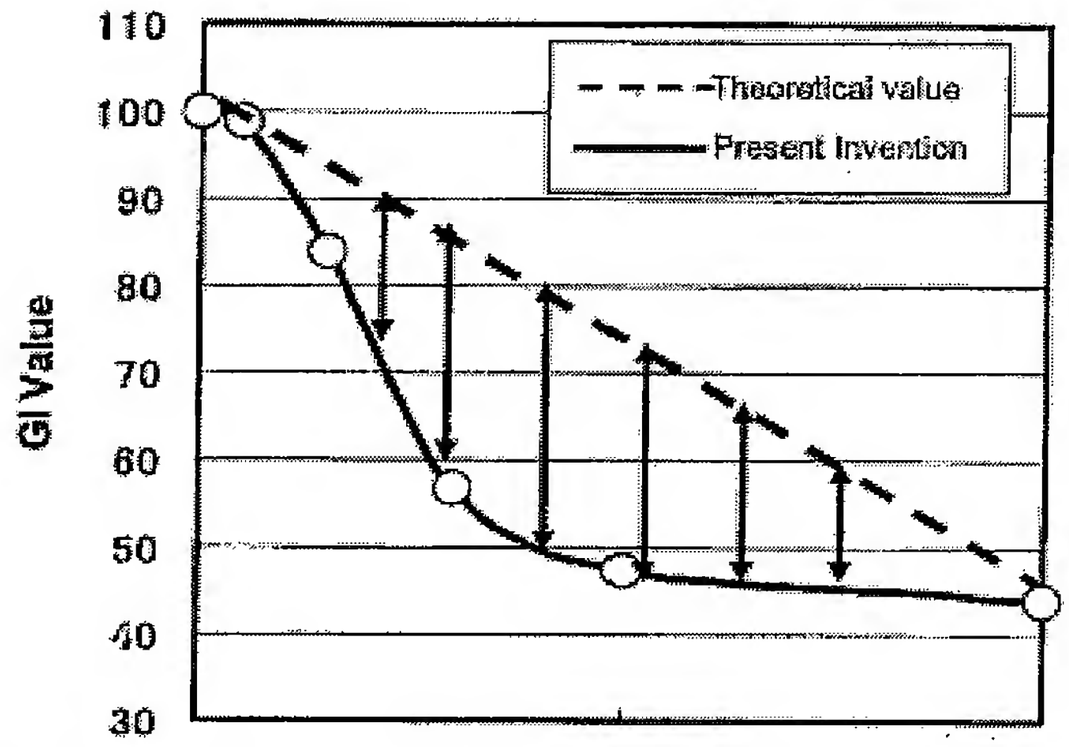
caused by ingesting carbohydrates other than palatinose and palatinose reduces the body fat accumulation caused by ingesting carbohydrates other than palatinose.

Specifically, the present invention provides a distinctive and wholly unexpected effect in that palatinose, by itself, reduces blood glucose level increase otherwise caused by the ingestion of at least one carbohydrate selected from the group consisting of maltose, sucrose, high fructose corn syrup, glucose, starch, dextrin, and branched dextrin (hereafter, collectively referred to as "maltose and the like"). Applicants explain, as follows, how it is that the present invention encompasses a "food material" and a "reducer of blood glucose level increase" in accordance with the present invention.

As is known, palatinose has a Glycemic Index (GI) of 44 and exhibits a gentler blood glucose level increase than when glucose itself is ingested (See, e.g., "Exhibit C," at 81, left col., lines 1-18, of record). GI is a value expressed relative to 100, which corresponds to the area under the curve for blood glucose level increase by glucose (See, e.g., Figure 4 and ¶ [0064] of Applicants' disclosure as originally filed, and webpage titled "About Glycemic Index," http://www.glycemicindex.com/aboutGIprint.htm, downloaded September 23, 2008, 2 pages, labeled as "Exhibit E," of record).

When palatinose is ingested substantially simultaneously with glucose, the blood glucose level increase resulting from ingestion of these carbohydrates would be expected to yield a weighted average of the blood glucose level increase due to ingestion of glucose alone and of the blood glucose level increase due to ingestion of palatinose alone. This theoretical expected rise in blood glucose level is denoted by the dashed line (--) shown in Figure A below. Figure A is based, in part, on original Figure 4 of the above-captioned application (See also Applicant's specification as originally filed, at ¶ [0064]).

Fig. A. Relationship between GI value and palatinose ingestion amount



Palatinose	**0**	**25**	**50**
Glucose	**50**	**25**	**0**

Ingestion amount (g) of palatinose and glucose for an ingested carbohydrate weight of 50 g.

As shown in Figure A above, when palatinose is actually ingested substantially simultaneously with glucose, the corresponding GI value curve (i.e., the solid curve in Figure A) diverges considerably from the theoretically predicted curve (i.e., the dashed line) determined from the weighted average of glucose level increase for glucose ingested alone and palatinose ingested alone. In other words, palatinose reduces the blood glucose level increase caused by glucose ingestion, as observed in Figure A, because GI value has dropped from the theoretical curve by the amount indicated by the vertical arrows. The conclusion is, therefore, that palatinose by itself has the function of a "reducer of blood glucose level increase" because it reduces the blood glucose level increase following ingestion of glucose when ingested substantially simultaneously with glucose.

As would be immediately appreciated by a person of ordinary skill in the art, the present invention achieves an unexpected effect that wholly overturns conventional knowledge, and that provides the novel application of a "reducer of blood glucose level" wherein palatinose, by itself, reduces blood glucose level increase due to ingestion of maltose

and the like when ingested substantially simultaneously with maltose and the like. Thus, the present invention provides an unexpected "reducer of blood glucose level increase" and a "foodstuff" that diminishes the blood glucose level increase otherwise expected to be observed when maltose and the like is ingested with palatinose.

For all of the above reasons, the Lina Article, the Burke Patent and the Brendel Publication, either alone or in combination, cannot sustain a prima facie case of obviousness against Applicants' claimed invention.

III. CONCLUSION

In view of the present amendment, claims 1-11, 13-17 and 29-42 are in compliance with 35 U.S.C. § 112. Furthermore, the Examiner has failed to establish a prima facie case of anticipation, or of obviousness, against independent claims 1-8, 13 and 14 of the above-captioned application because neither the Lina Article, the Burke Patent nor the Brendel Publication teaches, or suggests, each and every limitation recited by these claims. Furthermore, neither the Lina Article, the Burke Patent nor the Brendel Publication teaches, or suggests, the subject matter of dependent claims 29-42.

For all of the above reasons, claims 1-11, 13-17 and 29-42 are in condition for allowance, and a prompt notice of allowance is earnestly solicited.

Questions are welcomed by the below-signed attorney for Applicants.

Respectfully submitted,

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